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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/765,564	01/27/2004	William Dubrul	GTEC 1001-5	8126
23470	7590	06/09/2009		
HAYNES BEFFEL & WOLFELD LLP			EXAMINER	
P O BOX 366			HOUSTON, ELIZABETH	
HALF MOON BAY, CA 94019				
			ART UNIT	PAPER NUMBER
			3731	
			MAIL DATE	DELIVERY MODE
			06/09/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/765,564

Applicant(s)

DUBRUL ET AL.

Examiner

ELIZABETH HOUSTON

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 March 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 6.7.10-16, 19, 20, 25-28 and 57-59 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 6.7.10-16, 19, 20, 25-28 and 57-59 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 6-16, 19, 20, 25, 28, 57-59 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The independent claims recite a "blood flow blocking element comprising a blood flow blocking surface with structural members which define openings therebetween". One interpretation is A), the blood flow blocking element is made up of a blood flow blocking surface (for example the membrane) *and* structural members which define openings (for example the struts of the malecot). However, some claims (claim 11, 19, 25, 28) go on to further claim a membrane, and clearly there are not two membranes disclosed in the specification. Another interpretation is: B) the blood flow blocking surface itself is made of the structural members with openings. In which case it is unclear how the structural members with openings can be the blood flow blocking surface, unless it is only meant to be interpreted as "partially" blocking blood flow. Since the specification does not recite the terminology "blood flow blocking surface" and therefore there is no clarification of the matter, examiner is left to determine how to interpret the claim to the best of her ability.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claim 6 is rejected under 35 U.S.C. 102(b) as being anticipated by Kavteladze (WO 95/27448). (For references in rejection please refer to US patent 5,683,411)

3. Kavteladze discloses the invention substantially as claimed including an occluder and a method of deploying an occluder that comprises: a catheter having a distal end (C5:L40) that is inserted into a body passageway, having a balloon-less blood flow blocking element (Figs 3, 4, 6, 9, 10; where the element is the entire device including the parabolic structures and the membrane) affixed to the catheter (the blood blocking element is joined to the distal end of the catheter when the element is inside the catheter during delivery; note that affixed merely requires that the blood blocking element be attached or joined to the distal end of the catheter and does not require that the element be "fixedly attached" to the distal end of the catheter), the blood flow blocking element comprising a blood flow blocking surface (in that the structural members provide a surface that can partially block the flow of blood) with structural members that define openings (10,11,40,41) and positioned near the distal end of the catheter, said blood flow blocking element having a radially compressed insertion state and a radially expanded, passageway sealing state (C5:L38-50), the step of radially expanding the blood flow blocking element being carried out without inflating a balloon using a fluid, and said blood flow blocking element in said radially expanded state

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having an outer distally facing, generally funnel surface extending out from said distal end of said catheter (10, 11, 40, 41), the funnel surface being the blood flow blocking surface (as explained above). The occluder *further* comprises an annular membrane (16, 42) contacting or around the structural members (see Fig. 9) that is an elastomeric impermeable membrane (C3:L8-15). The blocking element (structural member and membrane combined) completely blocks passage of material around the outside of the catheter.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. **Claim 7 and 28, 57-59 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kavteladze (US 5,683,411).**

6. Kavteladze does not disclose that the blood flow blocking element is malecot style. However, the instant disclosure describes this parameter as merely preferable and does not describe it as contributing any unexpected result to the occluder. As such this parameter is deemed a matter of design choice (lacking in any criticality) and well within the skill of the ordinary artisan, obtained through routine experimentation in determining optimum results.

7. Regarding claims 57-59, Kavteladze discloses the step of maintaining the catheter with the blood flow blocking element affixed thereto (during placement of the

catheter and delivery of the occluder, C4:L41-50), but does not explicitly disclose the step of radially contracting the blocking element and removing the catheter and the blocking element. However, it is old and well known in the art to partially deploy the implant from the catheter before realizing that it needs to be relocated, thus causing the user to retract the implant back into the catheter to more accurately locate it. It is inherent that the catheter would be removed from the body after the procedure. It is inherent, if not obvious that the blocking element would be removed from the body at some point in time.

8. Claims 10-16, 19, 20, 22-25 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kavteladze in view of Marks (US 5,108,420).

9. Kavteladze discloses the invention substantially as claimed as stated above except for an actuator. Kavteladze further states that the device is "ejected" from the catheter indicating the use of an actuator, but does not explicitly state the use of an actuator. However Marks discloses the delivery of an occluder that uses a delivery catheter (17) and an actuator (15 and 19) that extends through the lumen of the catheter that does not require inflating a balloon. The actuator extends distal of the blood blocking element (19 prior to deployment) and when moved in a proximal direction (C4:L21-39 states that 19 is pulled proximally while 15 is pushed), engages the blood blocking element (19 will continue to engage the occluder until it leaves the catheter as seen in Fig. 1) to switch from the retracted state to the expanded state.

It would have been obvious to incorporate an actuator to move the blood flow blocking element from the compressed state to the radially expanded state since it is well known in the art to use actuators to assist self-expanding devices out of the catheter. A person of ordinary skill has good reason to pursue the known options within his or her technical grasp if it yields predictable results.

10. Regarding claim 12 and 16, Kavteladze does not disclose that the blood flow blocking element is malecot style. However, the instant disclosure describes this parameter as merely preferable and does not describe it as contributing any unexpected result to the occluder. As such this parameter is deemed a matter of design choice (lacking in any criticality) and well within the skill of the ordinary artisan, obtained through routine experimentation in determining optimum results.

Response to Arguments

11. Applicant's arguments filed 03/02/09 have been fully considered but they are not persuasive. It seems from the arguments that applicant is trying to distinguish over the prior art by trying to define the membrane as the funnel surface that is the blood blocking surface, however as stated above, it is not so clearly defined in the claims. Applicant is requested to more clearly state whether the blood flow blocking surface is just part of the structural elements with openings or whether it is in fact the membrane.

12. Applicant states that the claims state that the blood flow blocking element is "affixed" to the catheter to try to distinguish the claimed invention from the prior art since is a device that is released from the catheter. However, examiner does not find the

terminology "affixed" so limiting and suggest language such as *fixedly attached to the distal end of the catheter*.

Conclusion

13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **ELIZABETH HOUSTON** whose telephone number is (571)272-7134. The examiner can normally be reached on M-F 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anh Tuan Nguyen can be reached on 571-272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/E. H./

Examiner, Art Unit 3731

/Anh Tuan T. Nguyen/

Supervisory Patent Examiner, Art Unit 3731

6/5/09